

Inventors: Yeaman and Shen  
Serial No.: 09/648,816  
Filed: August 25, 2000  
Page 4

### **REMARKS**

Claims 67-79 are pending in the above-identified application. Claims 70-74 and 76-79 stand withdrawn from consideration as directed to a non-elected invention. Claims 67-69 and 75 are presently being examined.

Claim 67 has been amended herein to clarify that the claimed antimicrobial peptide consists of an amino acid sequence having 13 to 74 amino acids. Claim 67 has further been amended to recite that the antimicrobial peptide includes synthetic analogues of the core sequence. The amendment to claim 67 is supported throughout the specification, for example, at page 42, lines 8-11, and adds no new matter. Applicants respectfully request entry of the amendment.

### **Rejections under 35 U.S.C. § 112, second paragraph**

The rejection of claims 67-69 and 75 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, respectfully is traversed. Applicants maintain that claims 67-69 and 75 are clear and definite to one possessing the ordinary level of skill in the art in view of the specification.

Applicants again point out that the U.S. Court of Appeals for the Federal Circuit has indicated in its numerous decisions on the issue that definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. *See, e.g., In re Marosi*, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 221 U.S.P.Q. 1 (Fed. Cir. 1984); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983); and *Atmel Corp. v. Information*

Inventors: Yeaman and Shen  
Serial No.: 09/648,816  
Filed: August 25, 2000  
Page 5

*Storage Devices, Inc.*, 198 F.3d 1374, 53 U.S.P.Q.2d 1225 (Fed. Cir. 1999) (district court failed to consider the knowledge of one skilled in the art when interpreting the patent disclosure).

The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe. That determination requires a construction of the claims according to the familiar canons of claim construction.

*All Dental Prodx, LLC v. Advantage Dental Prods.*, 309 F.3d 774, 779-80, 64 USPQ2d 1945, 1949 (Fed. Cir. 2002) (citations omitted).

The determination of whether a claim is invalid as indefinite “depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the specification.” See *N. Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1579 (1993) (citation omitted).

With regard to the assertion that the phrase “mimetics thereof” is indefinite, Applicants respectfully submit that this term, viewed by the skilled person in light of the specification and what was known in the art, is sufficiently clear and definite to meet the requirements of paragraph 112. According to the Federal Circuit, “[M]athematical precision is not required--only a reasonable degree of particularity and definiteness.” *Exxon v. US*, 265 F.3d 1371, 1381; 60 U.S.P.Q.2d 1272, 1279 (Fed. Cir. 2001). A reasonable degree of definiteness is provided to the skilled person viewing the phrase “mimetics thereof” by teaching, for example, at page 42, lines 12-21, that the invention peptides can be conformationally stabilized by replacing selected amino acid in the original peptide with amino acids that restrict the motion of the peptide chain, for example, beta-branched, N-methyl, alpha,beta-dehydro, alpha,alpha-dialkyl and D-amino acids. The specification also teaches that substitutions of D- or other unusual amino acids into the peptide templates can extend the half-life of an invention peptide. The skilled person would have understood with clarity that mimetics include peptidomimetics, peptoids, or other peptide-

Inventors: Yeaman and Shen  
Serial No.: 09/648,816  
Filed: August 25, 2000  
Page 6

like polymers as well as non-polymeric compounds upon which functional groups that mimic a peptide are positioned.

Another significant issue with regard to clarity is the knowledge of one skilled in the art when interpreting the patent disclosure. Notably, the Federal Circuit has overturned cases on the indefiniteness issue where the knowledge of one skilled in the art was not taken into account. *See Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 53 U.S.P.Q.2d 1225 (Fed. Cir. 1999). With regard to the art-knowledge, both the manufacture of peptidomimetics and the scope of the term itself were well known in the art as evidenced by the Exhibits previously submitted by Applicants.

Page 848, right column, final paragraph.

In view of the above, Applicants respectfully submit that the term "mimetics" was well known in the art at the time the subject application was filed such that the skilled person would understand the scope of claim 67 when the claim is read in light of the specification. Nevertheless, Applicants have amended claim 67 to replace the term "mimetics" with the phrase "synthetic peptide mimetics" to clarify that naturally occurring amino acids are not encompassed as mimetics of the invention.

In sum, Applicants respectfully submit that those skilled in the art would understand the scope of claims 67-69 and 75 when the claims are read in light of the specification. In view of the above remarks and exhibits, Applicants respectfully request that the Examiner remove the rejection of claims 67-69 and 75 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Inventors: Yeaman and Shen  
Serial No.: 09/648,816  
Filed: August 25, 2000  
Page 7

**Rejections under 35 U.S.C. § 102**

Applicants respectfully traverse the rejection of claims 67-69 and 75 under 35 U.S.C. § 102(b), as allegedly anticipated by United States Patent No. 5,409,898, to Darveau et al. The Office Action alleges that, since the claim does not define the “mimetics thereof,” any substituted peptide that retains antimicrobial activity would fall within the scope of the claim (current Office Action, mailed January 17, 2004, section 4, page 5).

Applicants respectfully disagree that the peptides set forth in the ‘898 patent, which differ from the claimed antimicrobial peptides by having non-identical natural amino acid residues at several positions qualify as mimetics of the claimed peptides. Mimetics are “chemical structures derived from bioactive peptides which imitate natural molecules.” Goodman and Ro, Exhibit A to Applicants’ response filed November 21, 2003, sentence bridging pages 804 and 805). A natural peptide having non-identical natural amino acid residues at several positions compared to the claimed antimicrobial peptide does not represent a mimetic of an antimicrobial peptide of claims 67-69 and 75. Furthermore, Applicants have amended claim 67 to replace the term “mimetics” with the phrase “synthetic peptide mimetics” to clarify that naturally occurring amino acids are not encompassed as mimetics of the invention.

Accordingly, removal of the rejection of claims 67-69 and 75 under 35 U.S.C. § 102(b), as allegedly anticipated by United States Patent No. 5,409,898, to Darveau et al. respectfully is requested.

Applicants respectfully traverse the rejection of claims 67-69 and 75 under 35 U.S.C. § 102(b), as allegedly anticipated by Kupsch et al., *EMBO J.*, 12(2): 641-650 (1993). The Office Action alleges that claims 67 and 68 are anticipated by the description in Kupsch et al. of a member of the variable opacity (Opa) outer membrane family of proteins that is designated OPA 65 and has 236 amino acids, including the core sequence ARYRKWK.

Inventors: Yeaman and Shen  
Serial No.: 09/648,816  
Filed: August 25, 2000  
Page 8

As set forth above, base claim 67 has been amended herein to clarify that the claimed antimicrobial peptide consists of an amino acid sequence having 13 to 74 amino acids. The Opa 65 peptide has 236 amino acids and, accordingly, does not fall within the scope of claim 67 and cannot anticipate either base claim 67 or dependent claim 68. Accordingly, Applicants respectfully request removal of the rejection of claims 67 and 68 under 35 U.S.C. § 102(b), as allegedly anticipated by Kupsch et al., *EMBO J.*, 12(2): 641-650 (1993).

Inventors: Yeaman and Shen  
Serial No.: 09/648,816  
Filed: August 25, 2000  
Page 9

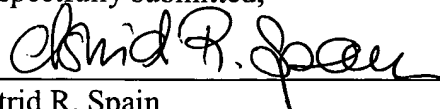
**CONCLUSION**

In light of the Amendments and Remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, he/she is invited to call the undersigned attorney.

Dated: April 19, 2004

McDERMOTT, WILL & EMERY  
4370 La Jolla Village Dr., Suite 700  
San Diego, California 92122

Respectfully submitted,



Astrid R. Spain  
Registration No. 47,956  
Telephone: 858.535.9001  
Facsimile: 858.535.8949